REMARKS

FORMAL MATTERS:

Claims 31-48, 50 and 52-82 are pending after entry of the amendments set forth herein.

Claims 1-30, 49 and 51 are canceled without prejudice.

Claims 32, 38, 48, 53, 57, and 69 are amended.

Claims 32, 48, 57 and 69 have been amended to delete reference to GM-CSF. A correction has been made to claim 43, and the dependencies of claims 38 and 53 have been modified.

Claims 83-90 are new. The wording of these new claims is based exactly on language in claims already pending in the application, except that there are provisos to exclude the cytokine GM-CSF (claim 83) or M-CSF (claim 84). Support for this amendment is found throughout the specification, as well as in the claims as originally filed, in that each of GM-CSF and M-CSF are positively recited as alternative elements. See, e.g., specification page 11, lines 21-24.

Authority for negative limitations based on positive recitation of alternative elements can be found in MPEP § 2173.05(i):

> If alternative elements are *positively* recited in the specification, then they may be explicitly *excluded* in the claims. See *In re Johnson,* 558 F.2d 1008, 1019, 194 USPQ 187, 194 (CCPA 1977) ("[the] specification, having described the whole, necessarily described the part remaining.").

The question before the court in the *Johnson* case was whether a claim that positively recited a genus but with the exclusion of a particular species had the priority benefit of an earlier application that positively recited both the genus and the species. The court held that the negative limitation in the claim was fully supported under the written description requirements of 35 USC § 112, ¶ 1 by a positive recitation in the priority application of the species.

> It is for the inventor to decide what *bounds* of protection he will seek. To deny appellants the benefit of their grandparent [1963] application in this case would, as this court said in *Saunders* [*In re Saunders*, 170 USPQ 213,220 (CCPA 1971)]: ". . . let form triumph over substance, substantially eliminating the right of an application to retreat to an otherwise patentable species . . .".
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> * * *

> Here, as we hold on the facts of this case, the "written description" in the 1963 specification supported the claims in the absence of the limitation, and *that specification, having described the whole, necessarily described the part remaining.* . . . [A]ppellants are, therefore, entitled to the benefit of their 1963 filing date under 35 USC § 120.[1]

The patent application as filed describes the practice of the claimed invention with a genus of membrane-associated cytokines, and explicitly refers to the species GM-CSF and M-CSF. Accordingly, under the authority of *In re Johnson,* claims 83-90 meet the written description requirement of 35 USC § 112 ¶ 1.

No new matter has been added.

INTERVIEW SUMMARY

Applicants wish to express their gratitude to Examiner Yaen for his time and efforts in the prosecution of this application, and particularly for the telephonic interview conducting on August 16, 2006 with the undersigned and Michael Schiff (representative of the licensee) and the subsequent in-person interview with the undersigned on October 17, 2006, with Michael Schiff participating by phone.

The Examiner was very helpful in both understanding the sole rejection of the claims, which is based on 35 USC §135(b). During the interviews, applicants presented proposed amended claims, and discussed how these claims did not claim substantially the same subject matter as any claim of Soo Hoo US 5,891,432.

During the interview the Examiner agreed that applicants' arguments in this regard were persuasive, and asked that applicants present these arguments for the record. The Examiner also asked applicants to remind the Examiner how the claims were patentable over the prior art of record, particularly as it related to M-CSF.

ALLOWABLE SUBJECT MATTER

Applicants are grateful to the Examiner for indicating that claims 55-64 and 78-81 are objected to for depending on rejected claims, but are otherwise allowable.

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[1] *In re Johnson,* 558 F.2d 1008, 1017-1019 (CCPA 1977), italics added.

REJECTIONS UNDER §135(B)

Claims 31-48,50,52-54,65-77. and 82 are rejected under 35 U.S.C. 135(b) as being made more than one year from the date on which U.S. Patent No. 5,891,432 ("Soo Hoo") was granted. This rejection is respectfully traversed as applied and as it may be applied to the pending claims.

Applicants respectfully submit that the claims as currently presented should not be subject to rejection under 35 USC § 135(b) with respect to the Soo Hoo patent (U.S. 5,891,432) for the reasons set out below. In addition, and at the Examiner's request, applicants indicate below how the present claims are distinguished from the prior art of record.

Claim 31 and its dependents:

- Claim 31 and its dependent claims do not refer to and are not limited to GM-CSF, and so are generic in this regard relative to the subject matter claimed in the Soo Hoo patent. The claims also require that the cell be inactivated, which is a feature not required by the Soo Hoo patent.
- Claim 31 and is dependents are distinguishable over cells comprising naturally occurring membrane M-CSF, *inter alia* because the cytokine is referred to as having a heterologous transmembrane domain.

Claims 35, 43, and their dependents:

- Claims 35 and 43, and their dependent claims, do not refer to a heterologous transmembrane domain, and so are generic in this regard relative to the subject matter claimed in the Soo Hoo patent.
- Claims 35 and 43, and thus their dependent claims, require that the tumor cell in the composition be an ovarian cancer cell, a brain cancer cell (claim 35) or a glioma, a glioblastoma, a gliosarcoma, an astrocytoma, or an ovarian cancer cell (claim 43).

Claim 55 and its dependents:

- Claim 55 and its dependent claims have not been rejected under §135(b). Claim 55 and its dependents are directed to a method for producing a pharmaceutical composition, and so are in a different statutory category from the subject matter claimed in the Soo Hoo patent.
- Claim 55 and its dependent claims are distinguishable over the manufacture of cells comprising naturally occurring membrane M-CSF, because the cytokine is referred to as having a heterologous transmembrane domain.

Claim 65:

- Claim 65 explicitly recites IL-4 -- not GM-CSF or M-CSF. For at least this reason claim 65 should not be subjected to a rejection under §135(b) since the subject matter claimed is not the same or substantially the same as that claimed in the Soo Hoo patent.

Claim 66:

- Claim 66 does not refer to a heterologous transmembrane domain, and so is generic in this regard to the subject matter claimed in the Soo Hoo patent.
- Since claim 66 explicitly recites GM-CSF, it does not encompass M-CSF.

New dependent claim 83:

- Claim 83 as presented explicitly excludes GM-CSF from its scope, and thus is not directed to the same or substantially the same subject matter as the Soo Hoo patent claims.

New claim 84 and its dependents:

- Claim 84 and its dependents do not refer to a heterologous transmembrane domain, and so are generic in this regard to the subject matter claimed in the Soo Hoo patent.
- Explicitly exclude M-CSF

For reasons explained earlier in the prosecution of this application, the claimed invention is also distinguishable from references that are directed towards administering cytokines or cytokine expressing nucleic acids in the treatment of cancer. Distinguishing features include the following:

- Some claims (e.g., independent claims 31 and dependents) require the membrane cytokine to have a *heterologous membrane domain.* Membrane-associated M-CSF referred to in previous disclosures did not have a heterologous membrane domain, as described in this application.

- Some claims (e.g., independent claim 84) explicitly *excludes M-CSF* as the membrane cytokine, or explicitly require the use of a different cytokine (e.g., independent claims 65 and 66).

- Some claims explicitly contain *tumor cells from particular cancers* not used in prior art studies (e.g., independent claims 35 and 43).

- The claims require that the cytokine-expressing cells have been *inactivated to prevent proliferation*. This is distinguishing from experiments in which membrane cytokine was expressed in live tumor cells as part of a tumor challenge.

- The claims require that the cytokine expressing cells be part of a *pharmaceutical composition formulated for human administration*. This distinguishes the claimed invention from experiments directed towards use of nucleic acid vectors for treatment of cancer.

Thus, the claims now pending in this application are not subject to rejection under 35 USC § 135(b) with respect to the Soo Hoo patent (U.S. 5,891,432), and are distinguishable over all the art of record in this application. Allowance of the application is respectfully requested.

CONCLUSION

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number IRVN-001DIV.

Respectfully submitted,
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Date: Nov 9, 2006

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